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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/266,543	03/11/1999	JOHN W. HOLADAY	05213-0075	5968

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EXAMINER

YAEN, CHRISTOPHER H

ART UNIT

PAPER NUMBER

1642

DATE MAILED: 01/14/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/266,543	HOLADAY ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Christopher H Yaen	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE \_\_\_\_ MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 16/28/02
- 2a) This action is **FINAL**.      2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 5-13, 15, 17-23 and 25-50 is/are pending in the application.
- 4a) Of the above claim(s) 30-49 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 5-13, 15, 17-23, 25-29 and 50 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some \* c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

- |                                                                                                |                                                                              |
|------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                    | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)           | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ . | 6) <input type="checkbox"/> Other: _____ .                                   |

**DETAILED ACTION**

1. The amendment filed 10/28/2002 (paper no. 24) is acknowledged and entered into the record. Accordingly, no claims have been canceled, and 1 claim has been newly added.

***Claim Objections***

2. The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

Misnumbered claim 30 been renumbered 50.

3. Claims 5-13, 15, 17-23, 25-50 are pending, claims 30-49 are withdrawn from consideration as being drawn to a non-elected invention. Therefore, claims 5-13, 15, 17-23, 25-29 and 50 are examined on the record.

***Claim Rejections Withdrawn- 35 USC § 112, 1<sup>st</sup> paragraph***

4. The rejection of claims 15-23 under 35 USC 112, 1<sup>st</sup> paragraph as lacking proper written description as it applies to the structural relation of sequence identification numbers to VEGF receptor binding domain, is withdrawn in view of the arguments presented by the applicant.

***Claim Rejections Withdrawn- 35 USC § 102***

5. The rejection of claim 6 under 35 USC 102 (b) as being anticipated by Senoo *et al* is withdrawn in view of the arguments set forth by the applicant.

***Claim Rejections Withdrawn- 35 USC § 112, 2<sup>nd</sup> paragraph***

6. The rejections of claims 5-13, 15, 17-23, and 25-29 under 35 USC 112, 2<sup>nd</sup> paragraph as being indefinite is withdrawn in view of the amendments to the claims.

***Claim Rejections Maintained-Double Patenting***

7. The rejection of claims 5,7-10, and 25-29 under the judicially created doctrine of obviousness type double patenting is maintained for the reasons of record. Applicant has requested that the rejection be held in abeyance until allowable subject matter is indicated at which time a terminal disclaimer will be submitted.

***New Claim Rejections- 35 USC § 112, 1<sup>st</sup> paragraph***

8. Claims 5-13, 15, 17-23, 25-29, 50 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The written description in this case only sets forth immunogenic peptides consisting of either FGF heparin binding domain or VEGF receptor binding domain and therefore the written description is not commensurate in scope with the claims which read on immunogenic fragments of either FGF heparin binding domain or VEGF receptor binding domain.

*Vas-Cath Inc. v. Mahurkar*, 19 USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the *invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117). The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116).

Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 USC 112 is severable from its enablement provision (see page 115).

With the exception of immunogenic peptides of either FGF heparin binding domain or VEGF receptor binding domain, the skilled artisan cannot envision the detailed structure of the encompassed immunogenic fragments and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and a reference to a potential method of isolating it. The amino acid sequence itself is required. See *Fiers v. Revel*, 25 USPQ 2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Lts.*, 18 USPQ2d 1016. Although these court findings are drawn to DNA art, the findings are clearly applicable to the claimed proteins.

Furthermore, although drawn specifically drawn to the DNA art the findings of *The Regents of the University of California v. Eli Lilly* (43 USPQ2d 1398-1412) are clearly applicable to the instant rejection. The court held that a generic statement which defines a genus of nucleic acids by only their functional activity does not provide an

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adequate written description of the genus. The court indicated that while Applicants are not required to disclose every species encompassed by a genus, the description of a genus is achieved by the recitation of a representative number of DNA molecules, usually defined by a nucleotide sequence, falling within the scope of the claimed genus. At section B(1), the court states that "An adequate written description of a DNA...requires a precise definition, such as by structure, formula, chemical name, or physical properties', not a mere wish or plan for obtaining the claimed chemical invention".

No disclosure, beyond the mere mention of immunogenic fragments of either FGF heparin binding domain or VEGF receptor binding domain is made in the specification. This is insufficient to support the generic claims as provided by the Interim Written Description Guidelines published in the June 15, 1998 Federal Register at Volume 63, Number 114, pages 32639-32645.

Therefore only FGF heparin binding domain or VEGF receptor binding domain peptides meets the written description provision of 35 USC 112, first paragraph.

***New Claim Rejections- 35 USC § 102***

9. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

10. Claims 5 and 6 are rejected under 35 U.S.C. 102(b) as being anticipated by Baird *et al* (U.S. Patent No. 5,252,718). Claims are drawn to a immunogenic composition comprising a peptide fragment of FGF and a pharmaceutical carrier, wherein the immunogenic peptide consists of SEQ ID No: 1 or 2. Baird *et al* teach a peptide that is

identical to SEQ ID No: 2, wherein they further teach that the peptides are heparin binding and can be used in conjunction with pharmaceutical carriers.

***New Claim Rejections- 35 USC § 103***

11. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

12. Claims 5-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baird *et al.* Claims are drawn to a immunogenic composition comprising a peptide fragment of FGF and a pharmaceutical carrier, wherein the peptide consists of either SEQ ID No: 1 or 2, wherein the pharmaceutical carriers comprise liposomes, colloidal gold, carrier proteins, and adjuvants.

Baird *et al* teach a peptide fragment that is identical to that of SEQ ID No: 2 and further teach that the peptides can be used in conjunction with pharmaceutical carriers. Although Baird *et al* do not specifically teach that the carriers can be liposomes, colloidal gold, carrier proteins, or adjuvants, one of skill in the art at the time the invention was made would have known to combine the peptides taught by Baird *et al* with other pharmaceutical carriers, such as liposomes, colloidal gold, carrier proteins, and adjuvants.

Therefore, it would have been *prima facie* obvious to one of skill in the art at the time the invention was made to combine the peptide taught by Baird *et al* with pharmaceutical carriers because Baird *et al* already suggest the use of pharmaceutical carriers but fails to specifically disclose the type of carriers that could be used in conjunction with the peptide. Furthermore, one of ordinary skill in the art at the time the

invention was made would have known to use other type of pharmaceutical carriers because the use of pharmaceutical carriers were already well known and well established in the art at the time of the invention. One of ordinary skill would have expected a reasonable amount of success in using other pharmaceutical carriers because the well established art teaches the relative success in using carriers with other proteins or peptide fragments.

***Conclusion***

No claim is allowed. This action is made **NON-FINAL** in view of the newly cited claim rejections.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher H Yaen whose telephone number is 703-305-3586. The examiner can normally be reached on Monday-Friday 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

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Chris John H/Y

Christopher Yaen

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January 9, 2003

*AS*  
ALI R. SALIMI  
PRIMARY EXAMINER